

Serial No.: 10/802,273

31162B

REMARKS

The Examiner has rejected claims 20-22 under 35 U.S.C. §112, ¶1, as failing to comply with the written description requirement. The Examiner maintains that the specification does not show that Applicant was in possession of the claimed invention of claims 20-22 at the time of the invention. Applicant respectfully disagrees.

Applicant understands that the issue is whether the specification reasonably conveys to a skilled artisan that the instant inventor actually had possession of the invention as now claimed. In Table 2, at page 6 of the specification, Applicant specifically describes a tri-phasic product with norgestimate having dosages in the range of 0.18-0.25 mg of norgestimate. Applicant clearly conveys the concept of altering the dosage of the progestin product to reduce the risk of ovarian cancer. (See page 13, lines 3-7). At page 35, line 19-24, Applicant clearly conveys to skilled artisan to alter the progestin dosage in an OCP product with norgestimate. Applicant states that one of the dosages has at least 0.5 mg of norgestimate. Applicant also states that the regimen for the “of this paragraph” can be “can have at least three phases, includes tri-phasic regimens.”

Applicant clearly conveys to one skilled in the art that one of the phases has at least 0.5 mg of norgestimate. Applicant has also previously disclosed in the specification that the non-altered phases have dosages in the range of 0.18-0.25 mg norgestimate. Thus, it is not a matter of obviousness or what would be readily understood. Rather, the specification reasonably conveys to a skilled artisan that for the phases that are not altered in accordance with the feature of increasing the progestin to increase apoptosis, the inventor had possession of an invention where the remaining phases are at the standard level of 0.18-0.25 norgestimate.

The Examiner has also issued a new ground of rejection under 35 U.S.C. §112, ¶2 for claim 22. Applicant has amended claim 22 to reflect “said another phase.”

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The Examiner has issued a new rejection under 35 U.S.C. §103 based on obviousness over Pasquale in view of Elliesen. The Examiner rejected claims 1-24 on the basis of this combination of references. Applicant respectfully disagrees with this rejection. The Examiner has shown no reason that would have prompted a skilled artisan to arrive at the claimed invention from anything taught in the prior art references. In fact, common sense would have suggest the opposite.

In this art, there has been a movement to decrease the amount of progestin and estrogen. If a skilled artisan were to decrease the amount of progestin in Example 2, the skilled artisan would do it for all three phases. There is no reason why a skilled artisan would reduce all but one of the phases in Example 2 to the levels shown in Example 4 of Pasquale. Moreover, there is nothing disclosed in any of these references that would suggest some combination of Examples 2 and 4 of Pasquale where one would use a substantially higher level of progestin in one phase from Example 2 and then two levels that are significantly lower from Example 4.

Nothing is taught in Pasquale regarding the weight of the user or anything else that would have prompted a person skilled in the art to arrive at the claimed invention. In fact, common sense would drive a skilled artisan in the opposite direction.

Applicant respectfully requests allowance of claims 1-24.

Please charge any fees associated with this filing to Deposit Account No. 10-0460.

Respectfully submitted,



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